UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

SIGMAPHARM, INC.,	:	
Plaintiff,	:	10 Civ_____( )
- against -	:	
MUTUAL PHARMACEUTICAL COMPANY, INC., UNITED RESEARCH LABORATORIES, INC., and KING PHARMACEUTICALS, INC.,	:	**(JURY TRIAL DEMANDED)**
Defendants.	:	

COMPLAINT

Plaintiff SigmaPharm, Inc. ("SigmaPharm"), by its undersigned attorneys, alleges for its Complaint as follows:

NATURE OF ACTION

1. This is an action for declaratory relief and monetary damages in connection with violations of federal antitrust law, violations of state law barring restraint of trade and unfair competition, and breach of contract arising from an agreement between defendants Mutual Pharmaceutical Company, Inc. ("Mutual"), United Research Laboratories, Inc. ("United"), and King Pharmaceuticals, Inc. ("King") under which Mutual and United agreed to cease or suspend commercialization of Mutual's generic competitor to King's branded drug, Skelaxin, and King agreed to pay and did pay Mutual and/or United substantial monetary sums. By virtue of this unlawful agreement, SigmaPharm has been damaged by being deprived of its contractual royalties on sales of Mutual's generic version of Skelaxin.

PARTIES AND JURISDICTION

2. Plaintiff SigmaPharm is a corporation organized and existing under the laws of the state of Delaware with its principal place of business at 15 Eagleton Farms Road, Newtown, PA 18940.

3. On information and belief, defendant Mutual is a corporation organized and existing under the laws of the state of Pennsylvania, having its principal place of business at 1100 Orthodox Street, Philadelphia, PA 19124.

4. On information and belief, defendant United is a corporation organized and existing under the laws of the state of Pennsylvania, having its principal place of business at 1100 Orthodox Street, Philadelphia, PA 19124.

5. On information and belief, defendant King is a corporation organized and existing under the laws of the state of Tennessee, having its principal place of business at 501 Fifth Street, Bristol, TN 37620.

6. This action arises under 15 U.S.C. 1 *et seq.*, the common law of the State of Pennsylvania, and California Business and Professions Code Section 17200 *et seq.*

7. This Court has subject matter jurisdiction to hear this action under 15 U.S.C. § 15(a) and 28 U.S.C. §§ 1331, 1337, and 1367.

BACKGROUND

Regulation of the Sale of Pharmaceutical Products by the United States Food and Drug Administration ("FDA")

8. The Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, codified at 21 U.S.C. § 355(j) and 35 U.S.C. § 27 1(e), commonly known as "Hatch-Waxman," requires FDA approval before a company may market or sell a pharmaceutical product in the United States. To obtain

approval to make and sell a new (or branded) drug, a company must file a new drug application ("NDA") with the FDA.

9. A generic drug may be approved for marketing if the FDA finds it to be "bioequivalent" to a branded drug. Two drugs are considered bioequivalent if they contain the same active pharmaceutical ingredient(s) and if there is no significant difference in the rate, and extent to which, the products are absorbed in the human body under similar experimental conditions, when administered at the same dose. *See* Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(8)(B).

10. Hatch-Waxman establishes a procedure for a branded-drug company to identify to prospective generic competitors patents that cover the branded drug or its use.

11. The FDA makes public the patents that branded-drug companies identify as covering a given product or its use in a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book").

12. To obtain approval to make and sell a generic version of a branded drug, a company can file an Abbreviated New Drug Application ("ANDA") with the FDA. With its ANDA, the generic drug applicant must provide to the FDA either (i) a certification under 21 U.S.C. 355(j)(2)(A)(vii)(I-IV) with respect to each patent listed in the Orange Book relating to the branded drug, or (ii) a statement under 21 U.S.C. 355(j)(2)(A)(viii) ("Section viii").

13. A certification under 21 U.S.C. 355(j)(2)(A)(vii)(I-IV) must make one of the following statements with respect to each patent, if any, listed in the Orange Book against the drug: (I) that no such patent information has been filed; (II) that the patent has expired; (III) that the patent will expire on a particular date; or (IV) that the patent is invalid or will not be

infringed by the manufacture, use, or sale of the drug product for which the ANDA is submitted. This last certification is known as a "Paragraph IV Certification."

14. Upon making a Paragraph IV Certification, the generic applicant must provide notice of that certification to the branded-drug company and to the owner of each patent against which the certification is made.

15. Hatch-Waxman contains provisions that govern the timing of FDA approval of generic applications containing a Paragraph IV Certification, based on whether and when a patent infringement suit is initiated. If neither the patent owner nor the branded-drug company files a patent infringement suit against the generic drug applicant within 45 days of receipt of notification of a Paragraph IV Certification, then the generic applicant is free to market its product upon final FDA approval of the ANDA.

16. If, however, the patent owner or branded drug company files a patent infringement suit against the generic drug applicant within 45 days of receipt of notification of a Paragraph IV Certification, then final FDA approval of the ANDA is automatically stayed until the earliest of: (i) patent expiration; (ii) a final court determination of non-infringement or patent invalidity; or (iii) the expiration of a 30-month period from the time the patent holder receives notification of a Paragraph IV Certification. This 30-month period effectively operates as an automatic statutory injunction to final FDA approval of an ANDA (the "30-Month Stay"), except that the court has discretion to shorten or prolong the stay if either party to the infringement action fails to reasonably cooperate in expediting the suit. *See* 21 U.S.C. § 355(j)(2)(B)(iii).

17. The first ANDA filer to submit a Paragraph IV Certification for a branded drug product receives a period of market exclusivity (the "180–Day Exclusivity Period"), during which the FDA cannot approve another ANDA on that branded drug product. The 180–Day

Exclusivity Period begins after the earlier of the date on which (i) the first ANDA filer begins commercial marketing of its generic version of the drug; or (ii) a court finds the patents claiming the brand name drug are invalid or not infringed.

18. If a patent listed in the Orange Book only covers methods of use of a drug, and not the drug itself, a prospective generic manufacturer may, as an alternative to certification under 21 U.S.C. 355(j)(2)(A)(vii), submit to the FDA a statement under 21 U.S.C. 355(j)(2)(A)(viii) ("Section viii") that the patent listed in the Orange Book does not claim a use for which the applicant is seeking approval. The filing of a Section viii statement does not trigger an obligation to notify the patent owner or the owner of the branded drug of the ANDA filing, nor does it subject the ANDA applicant to the possibility of a 30-month stay of approval by the FDA.

19. The FDA regulatory scheme presents significant barriers to market entry. For the owner of a branded drug, approval of an NDA requires that the FDA review and approve the results of costly clinical trials designed to determine the proposed drug's safety and efficacy. Such studies take several years to perform and can cost hundreds of millions of dollars to complete. For the owner of a generic drug, approval of an ANDA still requires that the FDA review and approve the results of bioequivalence studies. Such studies, while less onerous than clinical trials, are still costly and time-consuming. Moreover, the ANDA filer is subject to an automatic 30-month stay of FDA approval and costly litigation if the branded manufacturer sues the ANDA filer for patent infringement in response to a Paragraph IV Certification.

Benefits of Generic Competition

20. Although therapeutically equivalent to their branded counterparts, generic drugs are typically sold at substantial discounts from the price of the referenced branded drug. The first generic drug to enter the market often does so at a price 25 percent (25%) or more below that of the branded product. As additional generic drugs enter the market, generic drug prices may fall even further, often to less than fifty percent (50%) of the branded drug's price.

21. Because generic drugs are generally cheaper than their branded counterparts, government agencies and private purchasers have adopted policies to encourage or require pharmacists to substitute a generic drug for its branded counterpart. Many third-party payers of prescription drugs (e.g., managed care plans, Medicaid programs) encourage or insist on the substitution of generic drugs in lieu of their branded counterparts.

22. Upon marketing of the first generic equivalent of a branded drug, the resulting competition promptly leads to a significant decrease in the branded drug's market share, unit sales, and dollar sales.

23. A 1998 Congressional Budget Office Report estimates that in 1994 alone, purchasers saved $8-10 billion on prescriptions at retail pharmacies by purchasing generic drugs instead of the branded product.

Business Relationships between the Parties

24. SigmaPharm is engaged in the business of the development of pharmaceutical technologies and products.

25. Mutual, United, and King are engaged in the business of the development, manufacturing, sale, and distribution of pharmaceutical technologies and products.

The Employment Agreement

26. From March 22, 1999 to September 28, 2004, Spiridon Spireas, Ph.D. ("Dr. Spireas") was employed by Mutual to develop pharmaceutical products pursuant to an employment agreement between Dr. Spireas and Mutual dated March 22, 1999 (the "Employment Agreement").

27. Section 2(a) of the Employment Agreement provides:

> Employee [Dr. Spireas] shall serve the Company [Mutual] generally as Vice President of Research and Development. He shall be responsible for all of the Company's laboratory and research activities related to obtaining U.S. Food and Drug Administration approval of the Company's new products and shall have such other authority and responsibilities and perform such other duties as the Company reasonably may determine from time to time.

28. Section 9(d) of the Employment Agreement provides:

> Any and all writings, inventions, improvements, processes and/or techniques which Employee may make, conceive, discover or develop, either solely or jointly with any other person or persons, at any time during the term of this Agreement, whether during working hours or at any other time and whether at the request or upon the suggestion of the Company or otherwise, which relate to or are useful in connection with any business now or hereafter carried on or contemplated by the Company, including developments or expansions of its present fields of operations, shall be deemed to have been so conceived, discovered or developed by Employee in his capacity as an employee of SigmaPharm, Inc. in its capacity as 'Contractor' pursuant to that certain Development Agreement of even date herewith between SigmaPharm, Inc. and the Company, and shall be owned and treated as described therein.

The Development Agreement

29. On or about March 22, 1999, concurrently with execution of the Employment Agreement, Mutual and United entered into a development agreement with SigmaPharm (the "Development Agreement").

30. The Development Agreement makes provision for the ownership of "Innovations" developed by SigmaPharm, and for compensation to SigmaPharm in respect of such Innovations.

31. Section 2(a) of the Development Agreement provides:

> The term "Innovation" shall mean any invention, improvement or enhancement developed by Contractor [SigmaPharm] relating to the formulation of any of the Company's [Mutual's or United's] or United's pharmaceutical products which was not known to the Company or United at the time of development hereunder and presented to the Company by Contractor for which (i) the Company receives a U.S. patent, or (ii) the President of the Company determines, in his sole discretion, to be an "Innovation;" provided, however, that no such invention, improvement or enhancement that uses or is based upon the technology being licensed by the Company under the Hygrosol Agreement shall be deemed or constitute an Innovation.

32. Section 3 of the Development Agreement provides:

> The Company shall be the sole and exclusive owner of all right, title and interest in and to the Innovations in the United States market. Contractor shall remain the sole and exclusive owner of all right, title and interest in and to the Innovations in all markets other than the United States market.

33. Section 4(b) of the Development Agreement provides in pertinent part:

> With respect to any Innovation relating to technology with respect to any product for which an Abbreviated New Drug Application ("ANDA") would need to be filed to gain FDA approval to sell such product (even if the Innovation was previously used in another product), Contractor shall be entitled to receive royalty based on the sales of such product in the United States . . . ."
>
> (i) If, and so long as, there are no competitive generic products approved for sale in the United States, the Company, shall pay Contractor a royalty of 10% of the Gross Profit on all sales of such product in the United States which was manufactured by the Company, and for which the Company holds the ANDA;
>
> (ii) Beginning in the calendar month in which one competitive generic product is offered for sale in the United States, the royalty, subject to the same terms and conditions as set forth in clause (b)(i), shall be reduced to 5%;

34. Section 4(c) of the Development Agreement provides:

> With respect to any product which contains an Innovation which would be subject to a royalty under Sections 4(a) or 4(b) above, if such product was manufactured by the Company, if the Company licenses or sells the right to sell the product to a third party (or agrees to refrain from selling such product), Contractor shall be entitled to receive 25% of the Gross Profit of any licensing fees or royalties received by the Company in respect of such license, sale or agreement.

35. Section 4(d) of the Development Agreement provides in pertinent part:

> The Company shall pay the royalty to Contractor earned under Sections 4(a), 4(b) and 4(c) quarterly, within 30 days of the end of each calendar quarter.

36. Section 4(f) of the Development Agreement provides in pertinent part:

> In consideration of Contractor providing all necessary technical support to prepare the U.S. patent applications as described in Section 5(a) hereof, with respect to each such patent submission by or at the direction of the Company, the Company shall pay to Contractor, upon filing thereof, the sum of $10,000.

37. Section 5(a) of the Development Agreement provides in pertinent part:

> The Company shall have the right, at its expense, to control and prosecute and maintain any and all U.S. patent applications relating to Innovations, and to own any and all such applications and all U.S. patents issuing from said applications and all later filed applications, continuations, continuations-in-part, divisions, reissues or extensions thereof. Each of Contractor and its president, Dr. Spiridon Spireas, shall cooperate fully, at the Company's expense, in respect thereof, including without limitation, providing all necessary technical support in preparing all such U.S. patent applications . . . .

38. Section 1 of the Development Agreement provides in pertinent part:

> This Agreement shall commence on March 22, 1999 and shall remain in effect for so long as Dr. Spireas is employed by the Company pursuant to that certain Employment Agreement between the Company and Dr. Spireas dated of even date herewith (the "Employment Agreement"). Upon termination of Dr. Spireas' employment with the Company, this Agreement shall terminate provided . . . that any royalties payable to Contractor pursuant to Section 4 hereof for then-existing Innovations shall continue after the termination of the Agreement in accordance with the terms of Section 4.

King Owns and Markets Skelaxin

39. Skelaxin is a muscle relaxant approved by the FDA for the treatment of acute, painful, musculoskeletal conditions. Skelaxin has been marketed for more than 40 years.

40. The active pharmaceutical ingredient of Skelaxin is a chemical compound known as metaxalone. The compound metaxalone is not patented in the United States and is therefore in the public domain.

41. Since approximately mid-2003, Skelaxin has been owned, and its sales and marketing in the United States have been controlled, by King. For at least some time prior to mid-2003, Skelaxin was owned, and its sales and marketing in the United States were controlled, by Elan Pharmaceuticals ("Elan"). In 2008, sales of Skelaxin in the United States were approximately $450 million.

42. No generic versions of Skelaxin have been approved by the FDA for sale in the United States.

43. On information and belief, Skelaxin exhibits a unique pharmacokinetic and safety profile in that it is fast-acting, does not interfere with the motor activity used to maintain posture and balance, does not produce a loss of muscle tone, has a low incidence of side effects and drowsiness, and exerts no adverse cardiovascular effects. Moreover, Skelaxin contains an active pharmaceutical ingredient that is different from those found in other muscle relaxants, and consequently exhibits a distinct mechanism of action from those other drugs.

Dr. Spireas Develops a First Generic Equivalent of Skelaxin

44. In or about the first half of 2001, pursuant to the Development Agreement, Dr. Spireas developed for Mutual a first generic version of Skelaxin, namely, a metaxalone 400 mg

tablet that demonstrated bioequivalence to the Skelaxin 400 mg tablet under fasting conditions (the "First Mutual Generic Skelaxin").

Mutual Petitions the FDA to Require Generic Competitors to Show Fasting Bioequivalence

45. On or about March 6, 2001, Mutual filed a Citizen Petition requesting that the FDA withhold approval of any ANDA for a generic version of Skelaxin unless the applicant demonstrated that the proposed generic product and the branded drug were bioequivalent under fasting conditions.

46. On or about January 30, 2002, the FDA added the fasting bioequivalence requirement for generic Skelaxin 400 mg tablets.

Elan Requests that the FDA Require Food-Effect Label Changes for Skelaxin

47. On or about October 16, 2001, Elan applied to the FDA to revise the Skelaxin label by adding a reference to the increased bioavailability of Skelaxin when administered with food (the "Food-Effect Labeling").

48. On or about October 16, 2001, Elan applied to the FDA requesting that ANDA applicants for a generic version of Skelaxin be required to demonstrate that the proposed generic product and Skelaxin are bioequivalent under both fasting and non-fasting (fed) conditions.

49. On or about March 21, 2002, the FDA granted Elan's request and required ANDA applicants for a generic version of Skelaxin to demonstrate that the proposed generic product and Skelaxin are bioequivalent under both fasting and non-fasting (fed) conditions.

50. On or about June 18, 2002, the United States Patent and Trademark Office ("USPTO") issued U.S. Patent No. 6,407,128 (the "'128 Patent") to Elan. The '128 Patent is directed to methods of increasing the bioavailability of metaxalone by administering metaxalone with food.

51. In or about June 2002, the FDA approved the Food-Effect Labeling changes to the Skelaxin label that Elan had requested on or about October 16, 2001.

52. In or about June 2002, Elan listed the '128 Patent against Skelaxin in the Orange Book.

53. On or about June 12, 2003, Elan sold its Skelaxin product and franchise to King, and licensed to King the '128 Patent and Elan's rights to a pending patent application that ultimately would issue as U.S. Patent No. 6,683,102 (the "'102 Patent").

Dr. Spireas Develops an Additional Generic Version of Skelaxin

54. During the second half of 2002, pursuant to the Development Agreement, Dr. Spireas developed an additional generic version of Skelaxin, namely, a metaxalone 400 mg tablet that demonstrated bioequivalence to the Skelaxin 400 mg tablet under both fasting and non-fasting (fed) conditions (the "Second Mutual Generic Skelaxin").

King Blocks Mutual and Other Generic Manufacturers from Entering the Skelaxin Market

55. In or about December 2002, Eon Labs, Inc. ("Eon") filed an ANDA for a generic 400 mg Skelaxin product, with a Paragraph IV Certification concerning the '128 Patent. Eon became the first Paragraph IV filer against the '128 Patent.

56. On or about January 2, 2003, Elan commenced litigation against Eon in the United States District Court for the Eastern District of New York in response to Eon's Paragraph IV filing on the '128 Patent (the "Elan-Eon Litigation").

57. In or about February 2003, CorePharma, LLC ("CorePharma") also filed an ANDA for a generic 400 mg Skelaxin product, with a Paragraph IV Certification concerning the '128 Patent. CorePharma was the second Paragraph IV filer against the '128 Patent.

58. On or about March 7, 2003, Elan commenced litigation against CorePharma in the United States District Court for the District of New Jersey in response to CorePharma's

Paragraph IV filing on the '128 Patent (the "Elan-CorePharma Litigation"). On or about June 11, 2003, the Elan-CorePharma Litigation was transferred to the United States District Court for the Eastern District of New York.

59. In or about March 2003, Mutual filed an ANDA for the Second Mutual Generic Skelaxin. In its ANDA, Mutual included a Section viii Statement that the '128 patent listed in the Orange Book does not claim a use for which Mutual was seeking approval.

60. On or about January 27, 2004, the USPTO issued the '102 patent to King. The '102 Patent is directed to methods of providing metaxalone to patients while informing them that taking metaxalone with food results in higher blood levels of metaxalone.

61. In or about January 2004, King listed the '102 Patent against Skelaxin in the Orange Book.

62. In or about January 2004, Mutual filed a Paragraph IV Certification asserting, *inter alia*, that its generic Skelaxin equivalent would not infringe the '102 patent. That same day, Eon and CorePharma also filed Paragraph IV Certifications against the '102 Patent. Each of Mutual, Eon, and CorePharma became first Paragraph IV filers against the '102 Patent.

63. On or about March 12, 2004, King commenced litigation against Mutual in the United States District Court for the Eastern District of Pennsylvania in response to Mutual's Paragraph IV filing on the '102 Patent (the "King-Mutual Litigation").

64. In or about April, 2004, CorePharma withdrew its Paragraph IV Certification against the '128 Patent, and subsequently filed a Section viii Statement that the '128 patent listed in the Orange Book does not claim a use for which CorePharma was seeking approval.

65. On or about March 1, 2004, the FDA issued a ruling (the "Dear Applicant Letter"), in which it determined that "omission of information regarding fed-state bioavailability

from the labeling will not render the drug [Skelaxin] less safe for its approved uses . . ." and in which it authorized ANDA applicants for a generic version of Skelaxin to omit the Food-Effect Labeling.

Mutual Pursues its Rights to the Second Mutual Generic Skelaxin under the Development Agreement

66. On or about March 1, 2004, Richard Roberts, the President and CEO of Mutual ("Dr. Roberts"), directed Dr. Spireas to file a provisional patent application covering the Second Mutual Generic Skelaxin.

67. On or about March 8, 2004, Dr. Spireas filed a provisional patent application with the USPTO disclosing and claiming formulations of metaxalone, including the Second Mutual Generic Skelaxin.

68. On or about the end of February 2005, Mutual contacted Dr. Spireas, seeking his assistance in preparing and submitting a non-provisional patent application disclosing and claiming formulations of metaxalone, including the Second Mutual Generic Skelaxin.

69. Dr. Spireas worked with attorneys retained by Mutual to prepare a non-provisional patent application disclosing and claiming formulations of metaxalone, including the Second Mutual Generic Skelaxin, which was filed with the USPTO on or about March 8, 2005. In 2009, Dr. Spireas, through the same attorneys, filed further continuation applications with the USPTO disclosing and claiming formulations of metaxalone, including the Second Mutual Generic Skelaxin (collectively, the "United States Metaxalone Applications").

70. Mutual and United have asserted their right, pursuant to Section 3 of the Development Agreement, to own the United States Metaxalone Applications.

71. On or about December 18, 2009, pursuant to Section 3 of the Development Agreement, Dr. Spireas assigned to Mutual the United States Metaxalone Applications.

72. On or about January 11, 2010, pursuant to Section 4(f) of the Development Agreement, Mutual and United paid SigmaPharm $10,000 for Dr. Spireas' assistance in preparing the 2004 provisional and 2005 non-provisional applications disclosing and claiming formulations of metaxalone, including the Second Mutual Generic Skelaxin.

73. The Second Mutual Generic Skelaxin embodies an "Innovation" within the meaning of the Development Agreement.

Mutual Initially Opposes King's Efforts to Impose Label Changes on Generic Applicants

74. On or about March 18, 2004, King filed a Citizen Petition with the FDA requesting that the FDA (i) rescind its March 1, 2004 Dear Applicant Letter; (ii) require all ANDA applicants for generic Skelaxin to submit a Paragraph IV Certification against the '128 Patent; and (iii) prohibit the removal of the Food-Effect Labeling appearing on the Skelaxin label.

75. On or about March 18, 2004, King also submitted to the FDA a Petition for Stay of Action requesting that the FDA stay approval of any generic metaxalone products until the FDA had fully evaluated and ruled upon King's March 18, 2004 Citizen Petition.

76. On or about April 5, 2004, Mutual filed a submission with the FDA opposing King's Petition for Stay of Action and requesting that the FDA stay the approval of any additional Food-Effect Labeling until the FDA had fully evaluated King's March 18, 2004 Citizen Petition.

77. On or about April 15, 2004, King filed with the FDA a Supplemental Submission in support of King's March 18, 2004 Citizen Petition and its March 18, 2004 Petition for Stay of Action.

78. On or about May 13, 2004, King submitted to the FDA comments in opposition to Mutual's April 5, 2004 submission, in which Mutual had opposed King's March 18, 2004 Petition for Stay of Action.

79. On or about May 17, 2004, Mutual filed with the FDA a second submission opposing the Food-Effect Labeling requested by King for Skelaxin and any generic equivalents.

80. On or about July 21, 2004, King filed with the FDA a supplemental submission in support of King's March 18, 2004 Citizen Petition and its March 18, 2004 Petition for Stay of Action.

81. On or about February 15, 2005, Mutual submitted a letter to the FDA, opposing Food-Effect Labeling for Skelaxin and any generic equivalents.

King Informs Dr. Spireas that It has Settled with Some Generic Applicants

82. In or around October 2005, Dr. Spireas met with Mr. Brian Markison, the President and Chief Executive Officer (CEO) of King, and Mrs. Adriane Sax, King's Vice President of Business Development, at King's offices in Princeton, New Jersey.

83. At that meeting, Mr. Markison informed Dr. Spireas that King had settled the Elan-Eon Litigation and the Elan-CorePharma Litigation, and informed Dr. Spireas that Eon and CorePharma each would receive substantial annual payments from King. Mr. Markison also stated that King had approached Mutual to settle the King-Mutual Litigation and abandon its ANDA seeking approval to market the Second Mutual Generic Skelaxin.

Mutual and/or United Agree with King Not to Commercialize Generic Metaxalone

84. On or about December 6, 2005, Mutual and/or United entered into an agreement with King, pursuant to which Mutual and/or United agreed to cease or suspend

commercialization of the Second Mutual Generic Skelaxin, and King agreed to pay Mutual and/or United substantial monetary sums (the "Non-Commercialization Agreement").

85. Under the Non-Commercialization Agreement, King paid Mutual and/or United a first payment of $35 million and committed to making further periodic payments after January 1, 2006, based on sales of Skelaxin.

86. On information and belief, King has made and continues to make substantial additional payments to Mutual and/or United pursuant to the Non-Commercialization Agreement.

87. On information and belief, Mutual and/or United have received in excess of $200 million in payments to date pursuant to the Non-Commercialization Agreement.

Mutual Reverses Course and Supports King's Efforts to Impose Label Changes on Generic Applicants

88. On or about December 8, 2005, Mutual withdrew its prior opposition to labeling changes that King had been seeking from the FDA and instead submitted a letter to the FDA asking the FDA to reconsider its March 1, 2004 determination, which had authorized all ANDA applicants for generic Skelaxin 400 mg tablets to carve out Food-Effect Labeling from their proposed product labels.

89. In or about September 2006, Eon withdrew its ANDA for its 400 mg generic metaxalone product. The 30-Month Stay of FDA approval on Eon's ANDA for its 400 mg generic metaxalone product had expired in or about May 2005.

90. On or about October 17, 2006, the USPTO issued U.S. Patent No. 7,122,566 (the "'566 Patent") to Mutual.

91. The '566 Patent is directed to methods of providing a patient with metaxalone and informing the patient or a medical care worker about the potential for metaxalone to interact with drugs or foods that inhibit or induce the enzymes that metabolize metaxalone.

92. On information and belief, the '566 Patent is exclusively licensed by Mutual to King.

93. In or about October 2006, King listed the '566 Patent in the Orange Book.

94. On or about February 13, 2007, King filed with the FDA a supplemental submission in support of King's March 18, 2004 Citizen Petition and Petition for Stay of Action requesting that the FDA (i) prohibit removal of any information appearing on the Skelaxin label from the labeling of generic metaxalone products; and (ii) require generic metaxalone applicants to submit a Paragraph IV Certification challenging both the '128 and '102 Patents.

95. On or about May 2, 2007, Mutual submitted comments to the FDA supporting King's February 13, 2007 supplemental submission to the FDA.

96. On or about July 27, 2007, Mutual submitted a Citizen Petition to the FDA requesting that the FDA require labeling changes for Skelaxin by revising the label to include information about the potential for Skelaxin to interact with drugs or foods that inhibit or induce the enzymes that metabolize metaxalone.

97. On or about January 22, 2008, Mutual filed a Citizen Petition with the FDA requesting that the FDA refrain from approving any ANDAs for generic metaxalone products until results of certain in-vivo drug interaction studies were included in Skelaxin's labeling.

98. On or about July 18, 2008, the FDA denied Mutual's Citizen Petitions submitted to the FDA on July 27, 2007 and January 22, 2008.

FIRST CAUSE OF ACTION
(Sherman Act Section 1)

99. Paragraphs 1 to 98, above, are realleged and incorporated by reference as if set forth in full.

100. The Non-Commercialization Agreement is an unlawful combination or conspiracy among two or more separate entities that unreasonably restrains trade and affects interstate and/or foreign commerce.

101. The Non-Commercialization Agreement is a horizontal agreement between King and Mutual and/or United that allocates to King the United States market in Skelaxin and generic metaxalone equivalents.

102. By entering into the Non-Commercialization Agreement, King acted in concert with Mutual and/or United to unreasonably and illegally restrain interstate trade and commerce in the United States market for Skelaxin and generic metaxalone equivalents.

103. The Non-Commercialization Agreement produces anti-competitive effects, including at least maintaining a high price for Skelaxin and excluding competition in the United States market for Skelaxin by preventing entry of the generic metaxalone product covered by Mutual's ANDA.

104. The Non-Commercialization Agreement has injured SigmaPharm by depriving it of royalties that would have accrued from sales of the Second Mutual Generic Skelaxin. SigmaPharm's injury flows directly from the exclusion of competition, in violation of Section 1 of the Sherman Act, between Skelaxin and the Second Mutual Generic Skelaxin.

105. The relevant product market in which to assess the anticompetitive effects of King's and Mutual's and/or United's conduct concerning metaxalone is the market for Skelaxin and generic metaxalone equivalents. Other muscle relaxants do not share the unique

pharmacokinetic and safety profile of, and are not interchangeable with, Skelaxin and its generic equivalents.

106. The relevant geographic market in which to assess the anticompetitive effects of King's and Mutual's and/or United's conduct is the United States. The FDA's regulatory scheme for approving drugs for marketing in the United States, and the fact that marketing and sales of Skelaxin occur on a nationwide basis, establish the boundaries of the geographic market.

107. By virtue of the Non-Commercialization Agreement and King's and Mutual's and/or United's unreasonable restraint of trade, SigmaPharm suffered harm, including the loss of royalties that would have accrued to SigmaPharm under Section 4(b) of the Development Agreement on sales of Mutual's generic metaxalone product.

SECOND CAUSE OF ACTION
(Restraint of Trade under Pennsylvania Law)

108. Paragraphs 1 to 107, above, are realleged and incorporated by reference as if set forth in full.

109. By entering into the Non-Commercialization Agreement, King, Mutual and/or United acted in concert.

110. By preventing the entry of a Mutual generic metaxalone product into the United States market for metaxalone, the Non-Commercialization Agreement produced anti-competitive effects in the market for metaxalone in the United States and Pennsylvania.

111. The Non-Commercialization Agreement was entered into to illegally restrain trade in the market for metaxalone in the United States and Pennsylvania.

112. By virtue of the Non-Commercialization Agreement, SigmaPharm suffered harm, including the loss of royalties that would have accrued to SigmaPharm under Section 4(b) of the

Development Agreement on sales of Mutual's generic metaxalone product in the United States, including in Pennsylvania.

THIRD CAUSE OF ACTION
(Unlawful and Unfair Competition under California Business and Professions Code Section 17200 *et seq.*)

113. Paragraphs 1 to 112, above, are realleged and incorporated by reference as if set forth in full.

114. King and Mutual and/or United, through their business acts and practices, have engaged in unlawful competition by entering into the Non-Commercialization Agreement and preventing the entry of a Mutual generic metaxalone product into the United States market for Skelaxin and its generic equivalents in violation of federal antitrust law and state statutory and common law.

115. King and Mutual and/or United, through their business acts and practices, have engaged in unfair competition by entering into the Non-Commercialization Agreement and preventing the entry of a Mutual generic metaxalone product into the United States market for Skelaxin and its generic equivalents.

116. King's and Mutual's and/or United's entry into the Non-Commercialization Agreement is unfair because (i) the Non-Commercialization Agreement produces anti-competitive effects, including at least maintaining a high price for Skelaxin and precluding competition in the United States market for Skelaxin by preventing entry of the generic metaxalone product that is the subject of Mutual's ANDA, and (ii) the harm flowing from the Non-Commercial Agreement outweighs any alleged benefits.

117. By virtue of King's and Mutual's and/or United's unlawful and unfair business acts and practices, SigmaPharm suffered the loss of royalties that would have accrued to

SigmaPharm under Section 4(b) of the Development Agreement on sales of Mutual's generic metaxalone product in the United States.

118. By virtue of King's and Mutual's and/or United's unlawful and unfair business acts and practices, Mutual has received substantial sums from King.

119. By virtue of King's and Mutual's and/or United's unlawful and unfair business acts and practices, King has made substantial profits from its ability to maintain an elevated price for Skelaxin.

FOURTH CAUSE OF ACTION
(Breach of Contract under Pennsylvania Law)

120. Paragraphs 1 to 119, above, are realleged and incorporated by reference as if set forth in full.

121. Mutual and United have failed to pay SigmaPharm any portion of the licensing fees and royalties they have received from King pursuant to the Non-Commercialization Agreement.

122. Mutual and United breached the Development Agreement by failing to pay to SigmaPharm 25 percent (25%) of the licensing fees and royalties they received from King pursuant to the Non-Commercialization Agreement.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that this Court:

A. Declare, adjudge and decree that Mutual, United, and King have violated federal antitrust law;

B. Declare, adjudge and decree that Mutual, United, and King have violated Pennsylvania common law;

C. Declare, adjudge and decree that Mutual, United, and King have violated California Business and Professions Code Section 17200 *et seq.*;

D. Declare, adjudge and decree that Mutual and United have breached the Development Agreement;

E. Award SigmaPharm money damages, including treble damages, for the violation by Mutual, United, and King of federal antitrust laws;

F. Award SigmaPharm money damages for the violation by Mutual, United, and King of Pennsylvania common law;

G. Award SigmaPharm restitution damages for the violation by Mutual, United, and King of California Business and Professions Code Section 17200 *et seq.*;

H. Award SigmaPharm money damages for breach of the Development Agreement;

I. Award SigmaPharm attorneys' fees; and

J. Grant such other and further relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demands trial by jury of all matters that are triable as of right to a jury.

Dated: January 29, 2010

Gregory J. Lavorgna (PA ID. 34874)
Andrea L. D'Ambra (P.A. ID. 93385)
DRINKER BIDDLE & REATH LLP
One Logan Square, 18th and Cherry Streets
Philadelphia, PA 19103
Telephone: (215) 988-2700
Facsimile: (215) 988-2757
Email: gregory.lavorgna@dbr.com
Email: andrea.dambra@dbr.com
Attorneys for SigmaPharm, Inc.

Of Counsel:
Stephen S. Rabinowitz
Randy C. Eisensmith
FRIED, FRANK, HARRIS, SHRIVER & JACOBSON LLP
One New York Plaza
New York, New York 10004
Telephone: (212) 859-4000